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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,576	08/27/2002	Lewis Dewi	NIDN-73247	3162

36335 7590 02/09/2004

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,576	DEWI ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2001 and 27 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/21/01* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/27/02 wherein claims 2-15 were amended.

Note: Claims 1-15 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a radioactive source, method of preparing a radioactive source, and use thereof comprising a radioactive isotope of iodine in the form of iodide ions or and iodine-containing compound adsorbed on the surface of a non-radiation attenuating substrate with the proviso that when the iodine is in the form of iodide ions, then, the substrate is not an ion exchange resin.

112 FIRST PARAGRAPH REJECTION

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising the iodide/iodine in combination with substrates polyvinyl alcohol, zeolite, natural carbon, solidified carbonaceous material, and silica, does not reasonably provide enablement for all substrates and iodine containing compounds. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a radioactive source, method of making a radioactive source, and uses thereof comprising iodide or iodine containing compounds adsorbed on a non-radiation attenuating substrate provided that when the iodine is in the form of iodide ions, then the substrate is not an ion exchange resin.

(2) State of the prior art

The references do not indicate which specific classes of compounds which are iodine/iodide-substrate combinations are compatible with the instant invention. (3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claims 1, 11, and 14 encompass a vast number of possible iodine-containing compounds and substrates.

Applicant's specification does not enable the public to make or use such a vast number of possible compound-substrate combinations.

(4) Level of predictability in the art

The art pertaining to the dyes binding to chitin-containing organisms is highly unpredictable. Determining the various iodine-containing compounds and/or substrates that will are useful in the instant invention requires various experimental procedures and without guidance that is applicable to all iodine-containing compounds and substrates, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claims 1, 11, and 14 encompass a vast number of iodine-containing compounds and substrates. Applicant's limited guidance does not enable the public to prepare such a numerous amount of iodine-containing compounds and substrate combinations. There is very little directional guidance in the specification since a very limited number of substrates were utilized. Hence, there is no enablement for all possible permutations and combinations of the iodine-containing compounds and substrate combinations.

(6) Existence of working examples

Independent claims 1, 11, and 14 encompass a vast number of iodine-containing compounds and substrate combinations. Applicant's limited working examples do not enable the public to prepare such a numerous amount of iodine-containing compounds and substrate combinations. While Applicant's claims encompass a plethora of possible iodine-containing compounds and substrate combinations, the specification provides

only for the substrates polyvinyl alcohol, zeolite, natural carbon, and solidified carbonaceous material, and silica, in combination with iodine/iodide.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible iodine-containing compounds and substrates known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTION

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on a multitude of iodine-

containing compounds, non-radiation attenuating substrates, and brachytherapy sources (see independent claims 1, 11, and 14). In addition, dependent claim 7 reads on any possible iodohalogen compound, organic compound containing a carbon-iodine bond, iodoso-compound, diaryliodinium salt, N-iodoamide, iodoxyl aryl compound, or covalently bonded inorganic iodide compound. Dependent claim 8 reads on a multitude of possible glassy materials zeolite-type trivalent metal silicate and radiation resistant polymers. Hence, one cannot readily ascertain what is being claimed in the instant invention. Thus, one of ordinary skill in the art cannot ascertain what is encompassed in the claims as written. Applicant is respectfully requested to clarify the claims in order that one may determine what is being claimed and conduct a thorough search of the claimed invention.

103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suthanthiran et al (US Patent No. 4,994,013).

Suthanthiran et al disclose radioactive seeds useful for medical treatments. The radioactive seed is comprised a metallic detectable marker (i.e., tungsten) coated

on a radioactive absorbing material (i.e., carbon) in a binder. The pellets are encapsulated in a material (see entire document, especially, abstract; column 2, lines 13-21). In the background of Suthanthiran et al, it is disclosed that brachytherapy sources are known to provide an effective method of treating diseased tissue (column 1, lines 7-10). Also, the background discloses that radioactive iodine sources generally comprise a container for a carrier body of radioactive material and an x-ray marker. The container is generally made from titanium or stainless steel which provides good mechanical strength to the container with minimum absorption of radiation (column 1, lines 26-31). Suthanthiran et al disclose that one aspect of their invention is coating the radioactive absorbing material onto a metal substrate (column 2, lines 2-3). The radioactive absorbing material may be any material which will absorb another fluid radioactive material. Possible radioactive absorbing materials include carbon, activated carbon or charcoal, and ion-exchange resins (column 2, lines 57-61). A binder material which can readily bond to the substrate and absorb radioactive material without disintegrating or breaking away from the substrate is selected (column 3, lines 1-7). The metallic radio opaque marker rods are coated with the binder and radioactive absorbing material (i.e., carbon and cellulose acetate) in an airborne tumbling process (column 3, lines 55-58). The radioactive material to be absorbed into the matrix of the pellet's internal structure is preferably I-125 (column 4, lines 11-12). Each pellet is capable of absorbing I-125 in amounts in excess of about 50 mCi (column 4, lines 51-52). In order to obtain the desired radioactivity, the carbon-coated pellets are loaded with a solution of one of the suitable radioactive materials (i.e., I-125) at a desired

concentration (i.e., 500 mCi/ml) [column 4, lines 54-57]. The amount of radioactivity in each pellet may vary from about 0.1 to about 1000 mCi (column 5, lines 3-5). The encapsulated seed may be implanted into a subject in the desired treatment area (column 5, lines 25-26). Thus, both Applicant and Suthanthiran et al disclose the generating of a radioactive source, method of making the source, and uses of the source as set forth in independent claims 1 and 11. It should be noted that Suthanthiran et al disclose radioactive seeds that may be absorbed onto a non-radiating substrate that is not an ion-exchange resin.

9. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coniglione (US Patent No. 5,713,828).

Coniglione discloses a brachytherapy device that is formed form a hollow tub shaped seed substrate. The brachytherapy device is inherently radioactive and facilitates medical application and improved safety for patients and medical personnel (see entire document, especially, abstract; column 1, lines 6-8; column 4, lines 26-28; column 6, lines 29-32). In the background of Coniglione, it is disclosed that brachytherapy is applied in the treatment of atherosclerosis to inhibit restenosis of blood vessels after balloon angioplasty or other treatments to open occluded or narrowed vessels (column 1, lines 33-36). One embodiment of Coniglione is a central tube shaped substrate formed from a material that is essentially transparent to the radiation emitted by the therapeutic isotope. Possible materials include titanium and carbon (column 5, lines 55-60). The radioactive material is coated on the outer surface of the

hollow tube shaped seed substrate and is protected by the sealing layer. One possible radioisotope is I-125 (columns 5-6, bridging paragraph). When the therapeutic radioisotope to be used is I-125, a uniform layer of silver is first deposited onto the outer surface of the hollow tube shaped seed substrate. Seed activity may range from 0.1 to 100 millicuries per seed (column 12, lines 39-50). Coniglione discloses that brachytherapy sources for the medical therapeutic applications of radiation are possible and should occur when the radioactive source is entirely sealed to prevent escape of the radioisotope (columns 12-13, bridging paragraph). Thus, both Applicant and Suthanthiran et al disclose the generating of a radioactive source, method of making the source, and uses of the source as set forth in independent claims 1, 11, and 14.

It would have been obvious to one of ordinary skill in the art to generate a radioactive source, method of making the source, and uses thereof as set forth in independent claims 1, 11, and 14 because Coniglione discloses a brachytherapy device that may be radiolabeled with iodine-125 and adsorbed on a non-radiation substrate that is not an ion exchange resin. In addition, Coniglione discloses in the background of the invention that brachytherapy may be applied in the treatment of atherosclerosis to inhibit restenosis of blood vessels after balloon-angioplasty or other treatments to open occluded or narrowed vessels. Hence, the skilled practitioner in the art would recognize that the radioactive source may be used in a method of inhibition of restenosis as set forth in Applicant's independent claim 14.

SPECIFICATION

10. The disclosure is objected to because of the following informalities: Applicant is respectfully requested to incorporate the continuing data in the first line of the specification.

Appropriate correction is required.

ABSTRACT

11. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

January 29, 2004